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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,185	10/19/2006	Mostafa Sadoqi	4424-4000US1	7843
27123	7590	10/05/2007		
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER LE, HOA T	
			ART UNIT 1773	PAPER NUMBER
			NOTIFICATION DATE 10/05/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<div style="border: 1px solid black; width: 150px; height: 20px; margin: 0 auto;"></div> <p style="text-align: center;"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/542,185	<b>Applicant(s)</b> SADOQI ET AL	
	<b>Examiner</b> H. T. Le	<b>Art Unit</b> 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.--

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>July 2005</u> . | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fluorescent dye as the entrapped dye in a polymeric nanoparticle, does not reasonably provide enablement for any other substances. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The entire specification describes fluorescent dyes as the material that is entrapped in a polymeric nanoparticle. There are no teachings or guidance as to any other materials that are suitable as the entrapped material in the polymeric nanoparticle. However, claims 1-19 recite "other substance" as the entrapped material. Therefore, the instant claims are broader than the enabling scope of the disclosure. Removal the phrase "or other substance" from the claims would obviate this rejection.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, the term "other substance" renders these claims indefinite because "other substance" includes everything. Therefore, the scope of the claim cannot be ascertainable.

Claim 6 is meaningless. How can a nanoparticle be in a micrometer range as nanoparticle by default definition is in nanometer range?

Claim 11 suffers the same deficiency of claim 1.

Other claims are deemed indefinite in view of their dependency upon claims 1, 2 or 11.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Examiner's Note: Because of the definition of nanoparticle in instant claim 6 (i.e. nanoparticle is in the micrometer range), for purpose of examination, the "nanoparticle" of the claimed invention is characterized as both "nanoparticle" and "microparticle".

6. **Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Henrichs et al (US 6,424,857), Baker (US 6,471,968), or Feldheim et al (US 6,602,932).**

Claims 1, 2 and 5 are so broad that any polymeric nanoparticles that can bound

to any substance (not necessarily fluorescent dye) will meet the claim limitations.

Henrichs: Teaches polymeric nanoparticles (nanoliposomes) attached to a fluorescent dye (col. 8, lines 8-18).

Baker: Teaches nanosized dendrimer (polymeric) that can bind to many substances.

Feldheim et al: Teaches polymeric nanoparticles with a shell on their surface which means that the particles are capable of entrapping a substance. See abstract.

**7. Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rembaum (US 4,267,235); Schwartz et al (US 5,073,498); or Wang et al (US 5,395,688).**

Rembaum, Schwartz, and Wang teach fluorescent microparticles comprising a fluorescent dye entrapped in a microparticle. See abstracts and claims.

**8. Claims 1-4 and 6-19 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Banerjee et al (US 6,964,747).**

Claim 1: Banerjee teaches a polymeric microparticle entrapping a fluorescent dye. See col. 6, lines 29-32 and 52-54.

Claims 2-4: PVA is taught at col. 8, lines 55-57.

Claim 5: See col. 10, lines 12-13 (100 nm to 100 microns).

Claim 6: the microparticle is in micrometer range by default definition and also disclosed in examples.

Claim 7: Green dyes are exemplified at col. 10, lines 32-35 which encompass ICG.

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Claims 8-9: targeting molecules including peptides, polypeptides and proteins are disclosed at col. 11, lines 27-30 and col. 15, lines 3-6.

Claim 10: pharmaceutically acceptable vehicle for the microparticle is suggested in Examples 16-18.

Claims 11-12: Banerjee teaches a method of entrapping a dye in a polymeric microparticle comprising: (a) forming a solution containing the microparticle and the dye; (b) dispersing the solution into a second solution; (c) allow a particle suspension to form wherein the particles entrap the dye; and (d) separating the dyed particles from the liquid phase by centrifugation. See col. 5, lines 29-54 and col. 12, lines 61-63.

Claim 15: See rejection to claim 1.

Claims 16-19 The dyed microparticles are useful in fluorescent imaging and bioassay (col. 7, lines 63-66 and col. 11, lines 27-40).

**9. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler et al (US 6,268,222).**

Claims 1-4: Chandler teaches polymeric nanoparticles which are stained with different fluorescent dyes. See abstract; col. 3, lines 9-15; and col. 4, lines 3-9.

Claims 5-6: See col. 3, lines 9-20

Claim 7: Cyanine dyes and near IR (NIR) fluorescent dyes (which encompass ICG) are taught at col. 4, lines 9-14 and 18-20 as most preferred.

Claims 8-10: Taggants are taught at col. 4, lines 45-50.

Claims 11-13: For method see examples.

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Claim 14: poly(lactide-co-glycolide) (PLGA) is taught at col. 3, line 33 and near IR fluorescent dyes (which encompass ICG)\* are disclosed as particularly preferred at col. 4, lines 9-14.

Claims 15-17: See col. 4, line 30 to col. 5, line 5.

Claims 18-19: For cancer treatment, see col. 24, lines 34-42 where manufacturing drugs using the nanoparticles is suggested.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al (US 6,268,222) as applied to claims 1-19 above, and further in view of the discussion below.**

Chandler teaches a dyed microsphere comprising a microsphere entrapping a fluorescent dye. The microspheres comprise a PLGA (col. 3, line 33) The fluorescent dye preferably comprises a NIR fluorescent dye (col. 4, lines 8-14). Known NIR fluorescent dyes include ICG (see for example, USP 6,592,847 to Weissleder, claims 1 and 39). Therefore, one having ordinary skill in the art would have found it obvious from this teaching of chandler to assemble a PLGA nanoparticle-ICG dye complex.

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\* See US Patent 6,592,847 to Weissleder, claims 1 and 39 where known NIR fluorescent dyes are exemplified.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. T. Le whose telephone number is 571-272-1511.

The examiner can normally be reached on 10:00 a.m. to 6:30 p.m., Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Thi Le/  
H. (Holly) T. Le  
Primary Examiner  
Art Unit 1773

September 28, 2007